



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

# CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (tisagenlecleucel) Prior Authorization Request Form #925

## Medical Policy #455 Adoptive Immunotherapy including CAR T-Cell Therapy

Please use this form to assist in identifying members who meet Blue Cross Blue Shield of Massachusetts' (BCBSMA's) medical necessity criteria for CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia (tisagenlecleucel). For members who do not meet the criteria, submit a letter of medical necessity with a request for [Clinical Exception \(Individual Consideration\)](#). Once completed, fax to:

<b>Medical and Surgical: 1-888-282-0780</b>	<b>Medicare Advantage: 1-800-447-2994</b>
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**CLINICAL DOCUMENTATION**  
Copies of clinical documentation that supports the medical necessity criteria for [CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia \(tisagenlecleucel\)](#) must be submitted with this form. **If the patient does not meet all the criteria listed below, please submit a letter of medical necessity explaining why an exception is justified.**

Patient Information	
Patient Name:	Today's Date:
BCBSMA ID#:	Date of Treatment:
Date of Birth:	Place of Service: Outpatient <input type="checkbox"/> Inpatient <input type="checkbox"/>

Physician Information	Facility Information
Name:	Name:
Address:	Address:
Phone #:	Phone #:
Fax#:	Fax#:
NPI#:	NPI#:

Please check off if the patient has the following diagnosis and <b>HAS RELAPSED<sup>a</sup></b> (second or later) or is <b>REFRACTORY<sup>b</sup></b> :	
CD19-positive B-cell acute lymphoblastic leukemia with morphologic marrow tumor involvement (≥ 5% lymphoblasts)	<input type="checkbox"/>

<sup>a</sup> Relapsed disease describes the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic cell transplant.

<sup>b</sup> Refractory (resistant) disease is defined as those patients who fail to obtain complete response with induction therapy, ie, failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts).

Please check off that the patient meets <b>ALL</b> the following criteria:	
Patient is 25 years old or younger at the time of infusion	<input type="checkbox"/>

Patient has not received prior treatment with tisagenlecleucel or any other gene therapy or is being considered for treatment with any other gene therapy	<input type="checkbox"/>
Patient has adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis	<input type="checkbox"/>

**CONTRAINDICATIONS**

<b>Please check off that the patient <u>DOES NOT HAVE ANY</u> of the following contraindications:</b>	
Burkitt lymphoma	<input type="checkbox"/>
Active hepatitis B, C, or any uncontrolled infection	<input type="checkbox"/>
Grade 2 to 4 graft-versus-host disease	<input type="checkbox"/>
Received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to tisagenlecleucel infusion	<input type="checkbox"/>
Active central nervous system 3 acute lymphoblastic leukemia (ie, white blood cell count $\geq 5$ cells/ $\mu$ L in cerebrospinal fluid with presence of lymphoblasts)*	<input type="checkbox"/>

\*Central nervous system (CNS) disease for B-cell acute lymphoblastic leukemia is defined by the following groups:

- CNS 1: Absence of blasts on cerebrospinal fluid cytopsin preparation, regardless of the white blood cell (WBC) count
- CNS 2: WBC count of less than 5/mL and blasts on cytopsin findings
- CNS 3: WBC count of 5/mL or more and blasts on cytopsin findings and/or clinical signs of CNS leukemia (eg, facial nerve palsy, brain/eye involvement, hypothalamic syndrome).

<b>Please check off if the facility is part of Risk Evaluation and Mitigation Strategy (REMS)</b>	
The facility delivering the therapy is certified by Novartis that it has an adequate REMS protocol (Risk Evaluation and Mitigation Strategy) to address a cytokine release syndrome and neurotoxicity	<input type="checkbox"/>

**CPT CODES/ HCPCS CODES/ ICD CODES**

<b>HCPCS Code Description</b>		
<b>codes:</b>		
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	<input type="checkbox"/>

Providers should enter the relevant diagnosis code(s) below:

Code	Description	
		<input type="checkbox"/>
		<input type="checkbox"/>

Providers should enter other relevant code(s) below:

Code	Description	
		<input type="checkbox"/>
		<input type="checkbox"/>